



1615/Imerge

PATENT
Customer No. 22,852
Attorney Docket No. 5273-95

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
)
Atsuchi Ozaki et al.) Group Art Unit: 1615
)
Application No.: 10/523,020 ✓) Examiner: To be Assigned
)
Filed: February 2, 2005)
)
For: Method for Treating Severe Heart) Confirmation No.: 7467
Failure and Medicament Therefor)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

Enclosed for the consideration of the Examiner in connection with the prosecution of this case is a copy of the Search Report issued in the corresponding international patent application together with a copy of each of the cited references and a Form PTO SB/08.

If there is any fee due in connection with this matter, please charge such fee to our deposit account 06-0916.

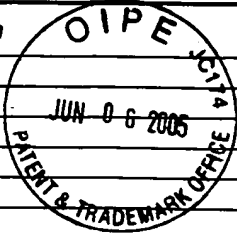
Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: June 6, 2005

By: 

Arthur S. Garrett
Reg. No. 20,338

IDS Form PTO/SB/08: Substitute for form 1449A/PTO			Complete if Known 	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			Application Number	10/523,020
			Filing Date	February 2, 2005
			First Named Inventor	Atsuchi Ozaki
			Art Unit	1615
			Examiner Name	To be Assigned
			Attorney Docket Number	5273-95
Sheet	1	of	1	

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS					
Examiner Initials	Cite No. ¹	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			

Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹		Translation ⁶
		L. A. SORBERA ET AL., "Tolvaptan," Drugs of the Future, 2002, Vol. 27, No. 4, pp. 350-357.	
		ALBERTO MARTINEZ-CASTELAO, "OPC-31260 Otsuka," Current Opinion in Cardiovascular, Pulmonary & Renal Investigational Drugs, " 1999, Vol. 1, No. 3, pp 423-432.	
		TOSHIO NISHIKIMI ET AL., "Effect of Long-Term Treatment with Selective Vasopressin V1 and V2 Receptor Antagonist on the Development of Heart Failure in Rats," Journal of Vardiovascular Pharmacology, 1996, Vol. 27, No. 2 pp. 275-282.	
		KEISHI SHIMIZU ET AL., "Effects of Oral OPC-31260, a Vasopressin V ₂ -Receptor Antagonist Administration on Arterial Baroreceptor Reflex in Conscious Intact and Adriamycin-Induced Heart Failure Rats, Naika Hokan, 1993, Vol. 40, No. 1, pp 7-11.	
		LOUISE M. BURRELL ET AL., "Long-Term effects of nonpeptide vasopressin V2 antagonist OPC-31260 in heart failure in the rat, American Journal of Physiology, 1998, Vol. 275, No. 1, pp. H-176-H182.	
		MAREO NAITOH ET AL., "Effects of oral AVP receptor antagonists OPC-21268 and OPC-31260 on congestive heart failure in conscious dogs, American Journal of Physiology, 1994, vol. 267, No. 6, Part 2, pp. H2245-H2254.	

Examiner Signature		Date Considered	
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



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Enclosed for the consideration of the Examiner in connection with the prosecution of this case is a copy of each of the 25 references set forth on the attached Form PTO/SB/08 except the U.S. Patents and patent publications.

The four Japanese patent publications are cited and discussed on page 2, lines 12-21 of the specification. Abstracts in English are also provided for each reference. A partial English translation is also provided for the Junkankika article.

If there is any fee due in connection with this matter, please charge such fee to our deposit account 06-0916.

Respectfully submitted,

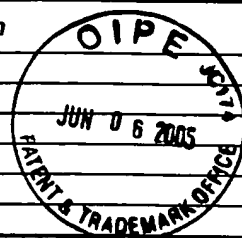
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Dated: June 6, 2005

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IDS Form PTO/SB/08: Substitute for form 1449A/PTO <h2 style="text-align: center;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="text-align: center;">(Use as many sheets as necessary)</p>			<div style="text-align: right;">Complete if Known</div> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Application Number</td> <td>10/523,020</td> </tr> <tr> <td>Filing Date</td> <td>February 2, 2005</td> </tr> <tr> <td>First Named Inventor</td> <td>Atsuchi Ozaki</td> </tr> <tr> <td>Art Unit</td> <td>1615</td> </tr> <tr> <td>Examiner Name</td> <td>To be Assigned</td> </tr> <tr> <td>Attorney Docket Number</td> <td>5273-95</td> </tr> </table>		Application Number	10/523,020	Filing Date	February 2, 2005	First Named Inventor	Atsuchi Ozaki	Art Unit	1615	Examiner Name	To be Assigned	Attorney Docket Number	5273-95
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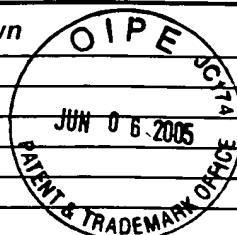
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		Number-Kind Code ² (if known)			
		US5,258,510	11-02-93	Hidenori Ogawa	
		US-5,753,677	05-19-98	Hidenori Ogawa	
		US-5,827,862	10-27-98	Yoshitaka Yamamura	
		US-2002128259A1	9-12-02	Ghazzi et al.	
		US-2003008860A1	1-9-03	Bakker-Arkema et al.	
		US-2004176354A1	9-4-04	Bakker Arkema et al.	

Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.

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		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
		JP-A-80641	03-22-94	Otsuka Pharmaceutical Co Ltd		X-Abstract
		WO 94/01113	01-20-94	Otsuka Pharmaceutical Co Ltd		
		JP-A-8-157368	06-18-96	Otsuka Pharmaceutical Co Ltd		X-Abstract
		JP-A-10-120592	05-12-98	Otsuka Pharmaceutical Co Ltd		X-Abstract
		JP-A-7-188021	07-25-95	Otsuka Pharmaceutical Co Ltd		X-Abstract
		WO 01/54677	08-02-01	Warner-Lambert Company		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation ⁶
		TARESH TANEJA ET AL., "Current Status of Acute Intravenous Therapy for Chronic Heart Failure Exacerbations," CHF September/October 1999, pp 199-207, 215.	
		LEONARD ARNOLDA ET AL., "Vasopressin and angiotensin II contribute equally to the increased afterload in rabbits with heart failure," Cardiovascular Research 1991; 25: pp 68-72.	
		MIHAI GHEORGHIADU ET AL., "Rationale and study design for a multicenter, randomized, double-blind, placebo-controlled study of the effects of tolvaptan on the acute and chronic outcomes of patients hospitalized with worsening congestive heart failure," American Heart Journal, Vol. 145, No. 2, February 2003; pp S51-4.	
		C. SERRADEIL-LE GAL ET AL., "Nonpeptide vasopressin receptor antagonists: development of selective and orally active V _{1a} , V ₂ and V _{1b} receptor ligands," Progress in Brain Research, Vol. 139, 2002, pp 197-210.	
		LOUISE M. BURRELL ET AL., "Vasopressin receptor antagonism - a therapeutic option in heart failure and hypertension," Experimental Physiology, March 2000; 85 Spec; pp 259S-265S.	
		YOSHITAKA YAMAMURA ET AL., "OPC-41061, a Highly Potent Human Vasopressin V ₂ -Receptor Antagonist: Pharmacological profile and Aquaretic Effect by Single and Multiple Oral Dosing in Rats," The Journal of Pharmacology and Experimental Therapeutics, December 1998, Vol. 287, No. 3, pp 860-867.	
		B. MAYINGER ET AL., "Nonpeptide vasopressin antagonists: A new group of hormone blockers entering the scene," Experimental and Clinical Endocrinology & Diabetes, " 1999, Vol. 107; pp 157-165.	
		MAREO NAITOH ET AL., "Effects of Chronic AVPV2R Blockade in Congestive Heart Failure in Sheep," Vasopressin and Oxytocin, Adv Exp Med Biol. 1998; 449, pp 445-446.	
		CHAGRIYA KITIYAKARA ET AL., Vasopressin V ₂ -receptor antagonists: panaceas for hyponatremia?, Current Opinion in Nephrology and Hypertension, September 1997, Vol. 6, No. 5, pp 461-467.	
		DING-LI XU ET AL., "Upregulation of Aquaporin-2 Water Channel Expression in Chronic Heart Failure Rat," The American Society for Clinical Investigation, Inc. April 1997, Vol. 99, No. 7, pp 1500-1505.	

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Sheet	2	of	2		



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		The American Society for Clinical Investigation, Inc. April 1997, Vol. 99, No. 7, pp 1500-1505.	
		J. G. VERBALIS, "Vasopressin V ₂ receptor antagonists," Journal of Molecular Endocrinology, 2002, Vol. 29, pp 1-9.	
		J. DONAID ALBRIGHT ET AL., "Recent Advances in the Discovery and Development of Vasopressin Antagonists: Peptide and Nonpeptide V _{1a} and V ₂ Receptor Antagonists," Current Pharmaceutical Design, 1997, Vol. 3, pp 615-632.	
		JUNKANKIKA 41, 150-154, 1997.	Partial translation

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